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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,981	08/29/2005	Lionel Vedrine	P-5753	5214
<div>7590      01/10/2008</div> <div>David W Hightet Becton Dickinson and Company 1 Becton Drive-MC 110 Franklin Lakes, NJ 07417</div>				
			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/520,981

Applicant(s)

VEDRINE, LIONEL

Examiner

Bhisma Mehta

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for holding the needle in position, the means for holding the container in position, and the respective means for operating said means of holding the needle in position and said means of holding the container in position must be shown or the feature(s) canceled from the claim(s). Also, the pierceable zone of the piston and the body forming a distal wall perpendicular to the axis of the needle must be shown or the feature(s) canceled from the claim(s). The needle-supporting part with at least one locking means and the at least one tab that comprises a locking means able to engage with that of the needle-supporting part must be shown or the feature(s) canceled from the claim(s). The engagement means integral with the plunger and the at least one tab comprising the engagement means must also must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Applicant has indicated on pages 9 and 10 of the Remarks filed September 24 2007 that these claimed features are shown in the figures. However, it is unclear where these features are shown as the language used in the claims is not consistent with the language which is used in the specification for the description of the figures.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because it contains legal phraseology, i.e., the use of "said retracted position" in lines 9-10. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities: The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)).

Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the second configuration of the piston or relative position of the piston and the container being such that it allows the product to pass out of the container without the piston being pierced.

***Claim Objections***

6. Claims 1-8 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification. The specific means-plus-function being objected to is the respective means for operating said means of holding the needle in position of claim 1, the spring means for moving the needle and the container to the retracted position of claim 5, the locking means of claim 1, and the engagement means of claim 8. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al (U.S. Patent No. 6,981,963). Barker et al disclose a device for injecting a product having a body (130) with a hollow injection needle (112) and a container (150) containing the injectable product. The device also has a plunger (140) that slides in the body. The container (150) is closed at one end and is connected to the plunger (140).

Means for holding the needle in position and means for holding the container in position on the forward end of the container are provided on the device. Barker et al also disclose the device as including a piston (170) engaged in the container which is so shaped that, in a first configuration, closes the container and, in a second configuration, allows product to pass out of the container between itself and the container without the piston being pierced. The piston is spaced from, and not in contiguous contact with, the needle (112) with the piston being in the second configuration or position (Figure 16). Respective means for operating said means of holding the needle in position and said means of holding the container in position are in the form of the displacement of the needle retainer (120) along with the release of the container or the clip (200) (lines 33-40 of column 13 and Figures 12-16). The piston (170) in the second configuration as shown in Figures 14 and 15 has a pierceable wall or zone which allows the product to pass between the piston and the container. The piston has a peripheral zone which is the section of the piston which presses tightly against the wall of the container, as seen in Figure 13, and which is withdrawn, as seen in Figure 14. Barker et al also disclose the device as having spring means (126). The body forms a distal wall perpendicular to the axis of the needle, from which the needle projects. As to claim 7, the means for holding the needle in position comprise a needle-supporting part with at least one locking means in the form of the apertures (38 in Figure 5, also shown in Figure 13 at 126) and at least one tab (24 in Figure 6, 120 in Figure 12) that comprises a locking means, in the form of the protrusions of the tabs, able to engage with that of the needle-supporting part. The tabs (24 or 120) are moveable radially between a normal, radially

inward position as seen in Figure 15 and a radially outward position, as seen in Figure 16, where a zone of the plunger moves the tab radially out.

***Allowable Subject Matter***

9. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1-8 are have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.



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BM

KEVIN C. SIMONS  
SUPERVISORY PATENT EXAMINER

